

REMARKS

This communication responds to the final Office Action mailed August 30, 2005. In the Office Action claims 20-28 and 30-35 were rejected. Claims 21-22, 24, 32 are canceled, and claim 29 was previously canceled. Claims 36-42 have been added. Therefore, claims 20, 23, 25-28, 30-31, and 33-42 are pending.

In this communication, claims 20, 23, 25, 31, and 35 are amended. In particular, claim 20 has been amended to clarify the position of the upper fin, the channel-like pocket, and to add an anchoring plate. Claim 23 has been amended to clarify the peripheral edge of the upper fin and to add an anchoring plate. Claim 25 has been amended to clarify the radial and anchoring fins and the surface of the channel-like pocket. Claim 31 has been amended to clarify the shaft, the upper fin, and the anchoring plate. Claim 35 has been amended to clarify the area which skin cannot grow. Applicant's amendments to the claims does not add new matter. Furthermore, new claims 36-42 do not add new matter and are supported by the specification.

Rejection under 35 U.S.C. § 112

Claims 20-24 and 35 were rejected under 35 U.S.C. 112, second paragraph.

Applicant respectfully traverses the § 112, second paragraph rejection of the claims. However, in order to advance prosecution, Applicant has amended claims 20, 23, and 35, which are reflected in the accompanying amendments to the claims.

Rejection under 35 U.S.C. § 102

Claims 20 and 23 were rejected under 35 U.S.C. § 102(b) over Andreussi (U.S. Patent 5,064,417).

Claims 25, 31, 32, 33 and 35 were rejected under 35 U.S.C. § 102(b) over Bentley et al. (U.S. Patent 4,183,357).

Claim 25 was rejected under 35 U.S.C. § 102(b) over Hargest (U.S. Patent 3,461,869).

Claims 25 and 28 were rejected under 35 U.S.C. § 102(e) over Gifford III et al. (U.S. Patent 5,817,113).

Claims 25, 31, 32, 33, and 35 were rejected under 35 U.S.C. § 102(b) over Bokros (U.S. Patent 3,783,868).

Claims 25, 31-33, and 35 were rejected under 35 U.S.C. § 102(b) over Slivenko (U.S. Patent 4,108,173).

Applicant respectfully traverses the § 102 rejections of the claims. Applicant submits that the rejections of the claims is inappropriate because the above-cited references fail to disclose each element of the independent claims.

In particular, Andreussi discloses a device for fastening a catheter to an osteofibrous wall for drainage purposes. In Fig. 2 of Andreussi a washer means 4 and a foot 2 are depicted subcutaneously. Neither washer means 4, nor foot 2, are situated such that an edge extends over an area of a channel-like pocket enabling tissue in-growth substantially only in the channel-like pocket due to the extension of the edge. Therefore, Andreussi fails to disclose the requirements of independent claims 20, 23, and 31. In addition, Andreussi fails to disclose an anchoring plate radially extending from the lower fin that extends generally away from the skin as required by independent claims 20, 23, and 31.

Furthermore, Adreussi fails to disclose a radial and anchoring fin that are fixed, or a channel-like pocket formed between radial and anchoring fins for tissue in-growth having a rounded cross-sectional area and a rough channel surface as required by independent claim 25.

Bentley discloses a chronic transcutaneous implant assembly for enterostomies. In Fig. 6, Bentley discloses a flared base 66 and flange 70 having apertures 72. Bentley states "The flange 70 of the implant is then positioned between the dermis and the facia and sutured therein through apertures 72. With healing, the vascularized muscle tissue will grow through apertures 72 to form a secure vascularized biological anchor for the implant." Column 5, lines 49-55. Therefore, Bentley discloses a device having a flange that is sutured into tissue and is secured and surrounded by vascular in-growth. Bentley fails to disclose an upper fin, a lower fin, and a

channel-shaped pocket where an edge of the upper fin extends over an area of a channel-like pocket enabling tissue in-growth substantially only in the channel-like pocket substantially due to the extension of the edge as required by independent claims 20, 23, and 31.

Furthermore, Bentley fails to disclose a channel-like pocket formed between radial and anchoring fins for tissue in-growth having a rounded cross-sectional area and a rough channel surface as required by independent claim 25.

Hargest discloses a permanent skin exit device that includes passageways 18 that are “disposed at an oblique angle to the plane of groove 24, the inclination of the passageway being such that a cannula 14, when mounted in untensioned condition, will form a small acute angle with the external surface on the tissue when button 10 is anchored in such tissue.” Column 3, lines 71-75. Groove 24 is formed between upper portion 15 and lower portion 17 of button 10. Neither the upper, nor the lower portions of the button are formed as fins. Therefore, Hargest fails to disclose an upper fin and a lower fin that have a pocket formed between as required by the independent claims.

In addition Hargest fails to disclose “an upper fin encircling the shaft at a *central* position of the shaft and including a peripheral edge” as required by independent claim 20, an “anchoring part compris[ing] a generally *radially* protruding port fin, an anchoring fin, and a radial pocket with a gap” as required by independent claim 23. Furthermore, Hargest fails to disclose an anchoring plate as required by independent claims 20, 23, and 31.

Moreover, Hargest fails to disclose the rough channel surface required by independent claim 25.

Gifford III discloses devices for performing surgical joining of biological tissues in order to restore intercommunication between the tissues. The device in Gifford III is implanted and does not connect an infusion hose to outside the body as required by each of the independent claims.

Bokros discloses a percutaneous implant that includes a stem having an upper flange, a radial flange, and a collar located between the upper and radial flanges. The collar and radial

flange are located subcutaneously. Bokros fails to disclose “an upper fin encircling the shaft at generally the midpoint . . . wherein the upper fin extends over an area of said channel-shaped pocket such that tissue in-growth occurs substantially only within said channel-shaped pocket substantially due to the extension of the peripheral edge of the upper fin” as required by independent claim 20.

Bokros further fails to disclose “an radially arranged around the anchoring part, said plate including a periphery, whereby, when the device is implanted, the periphery is farther from the skin than the rest of the anchoring plate” as required by independent claim 23, and an anchoring plate having “(a) a central portion disposed along a first radial plane with the lower radial fin; and (b) a peripheral portion disposed along a second radial plane positioned farther from the upper radial fin than the first radial plane” as required by independent claim 31.

With respect to independent claim 25, Bokros fails to disclose a “channel-like pocket having a rounded cross-sectional area and a rough channel surface.”

Slivenko discloses a blood access device having a tube, a flange, and a flexible flange attached over the flange. The flanges are located at right angles in relation to the tube and do not fall away from the skin. Therefore, Slivenko fails to disclose an anchoring plate having a periphery that is arranged farther from the skin than the base of the anchoring plate as required by independent claims 20, 23, and 31. Furthermore, Slivenko fails to disclose a “channel-like pocket having a rounded cross-sectional area and a rough channel surface” as required by independent claim 25.

Andreussi, Bentley, Hargest, Gifford III, Bokros, and Slivenko fail to disclose each requirement of independent claims 20, 23, 25, and 31. Therefore, Applicant requests that the § 102 rejections be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 26 and 27 were rejected under 35 U.S.C. § 103 (a) over Bentley as applied to claim 25, and further in view of Bokros U.S. Patent 3,783,868.

Claims 21, 22 and 24 were rejected under 35 U.S.C. § 103(a) over Andreussi as applied to claims 20 and 23, and further in view of Slivenko (U.S. Patent 4,108,173).

Claim 30 was rejected under 35 U.S.C. § 103(a) over Bentley or Hargest as applied to claim 25 and further in view of Broemer (U.S. Patent 4,365,356).

Claim 34 was rejected under 35 U.S.C. § 103(a) over Bentley, Slivenko or Bokros as applied to claim 31 and further in view Broemer (U.S. Patent 4,365,356).

Applicant respectfully traverses the § 103 rejections of the claims for at least the following reasons. Applicant submits that the above-discussed references when taken alone, or in combination, fail to suggest each requirement of the independent claims.

In particular, Bokros fails to remedy the deficiencies of Bentley. This is because neither Bokros nor Bentley teach an upper fin, a lower fin, and a channel-shaped pocket where an edge of the upper fin extends over an area of a channel-like pocket enabling tissue in-growth substantially only in the channel-like pocket due to the extension of the edge as required by independent claims 20, 23, and 31. Bokros fails to remedy the deficiencies of Bentley with respect to claim 25 because neither reference teaches a channel-like pocket formed between radial and anchoring fins for tissue in-growth having a rounded cross-sectional area and a rough channel surface.

Slivenko fails to remedy the deficiencies of Andreussi. Neither Andreussi nor Slivenko teach an anchoring plate radially extending from the lower fin that extends generally away from the skin as required by independent claims 20, 23, and 31. In addition, neither Andreussi nor Slivenko teach a channel-like pocket formed between radial and anchoring fins for tissue in-growth having a rounded cross-sectional area and a rough channel surface as required by independent claim 25.

Broemer fails to remedy the deficiencies of Bentley Hargest, Slivenko, and Bokros because Broemer teaches a prosthesis with a coating of a bio-active material and fails to teach any element of the independent claims.

Moreover, Broemer teaches away from providing an implantable device for connecting an infusion hose generally outside the body to a catheter generally inside the body. This is

because Broemer teaches a load-bearing prosthesis for replacing bone and teeth and includes a "multitude of areas on which the bone tissue can grow together with the prosthesis."

Therefore, Applicant requests that the § 103 rejections be withdrawn.

Dependent claims 26-28, 30, and 33-42 depend from their respective independent claims, and are distinguishable over the prior art for at least the reasons set forth above, and further in view of their additional recitations.

Conclusion

This communication generates additional claim fees for the added claims, and a check for the required claim fees is submitted herewith. The Commissioner is also hereby authorized to charge any additional fees and/or credit any overpayments associated with this communication to Deposit Account No. 04-1420.

The application is in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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Date: \_\_\_\_\_

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By: \_\_\_\_\_

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